

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
Sunstein, Bruce D.; Ash
SUNSTEIN KANN MURPHY & TIMBERS LLP
125 Summer Street
Boston, MA 02110-1618
SUNSTEIN KANN MURPHY & TIMBERS LLP
ETATS-UNIS D'AMERIQUE RECEIVED

SEP 24 2010

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 2860/187WO	Date of mailing (day/month/year) 20 September 2010 (20-09-2010)
International application No. PCT/US2010/025274	FOR FURTHER ACTION See paragraphs 1 and 4 below
International filing date (day/month/year) 24 February 2010 (24-02-2010)	
Applicant CONFORMIS, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest, the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within **20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the International Searching Authority

European Patent Office, P.B. 5818 Patentlaan 2
NL-2280 HV Rijswijk
Tel. (+31-70) 340-2040
Fax: (+31-70) 340-3016

Authorized officer

ACQUAVIVA, Laure
Tel: +49 (0)89 2399-5656

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 2960/187WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2010/025274	International filing date (day/month/year) 24/02/2010	(Earliest) Priority Date (day/month/year) 24/02/2009
Applicant CONFORMIS, INC.		

This International search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International search report consists of a total of 7 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of:



the international application in the language in which it was filed



a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

- b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).
- c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,



the text is approved as submitted by the applicant



the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,



the text is approved as submitted by the applicant



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figures of the **drawings** to be published with the abstract is Figure No. 20



as suggested by the applicant



as selected by this Authority, because the applicant failed to suggest a figure



as selected by this Authority, because this figure better characterizes the invention

- b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/025274

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

Disclosed herein are devices, systems and methods for the automated design and manufacture of patient-specific / patient-matched orthopedic implants (270, 10). While the embodiments described herein specifically pertain to unicompartamental resurfacing implants for the knee, the principles described are applicable to other types of knee implants (including, without limitation, other resurfacing implants and joint replacement implants) as well as implants for other joints and other patient-specific orthopedic applications.

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2010/025274

A. CLASSIFICATION OF SUBJECT MATTER
 INV. A61F2/38 A61F2/30
 ADD. A61B19/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2008/021494 A2 (SMITH & NEPHEW INC [US]; MC COMBS DANIEL L [US]; MELTON MARK [US]; JAM) 21 February 2008 (2008-02-21) paragraphs [0155] - [0157], [0161] - [0169], [0175] - [0190], [0196], [0197] figures 1,2,7,8,11-13 -----	1-16
X	US 2003/236473 A1 (DORE SYLVIE [CA] ET AL) 25 December 2003 (2003-12-25) figure 3 paragraphs [0028] - [0035] -----	1-16
X	US 2007/118243 A1 (SCHROEDER JAMES [US] ET AL) 24 May 2007 (2007-05-24) figures 1,2,8 paragraphs [0066] - [0081] paragraphs [0049] - [0059] ----- -/-	1-4,8-16



Further documents are listed in the continuation of Box C



See patent family annex

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claims) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

I later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

11 June 2010

Date of mailing of the international search report

20/09/2010

Name and mailing address of the ISA/
 European Patent Office, P.B. 5618 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel: (+31 -70) 340-2040,
 Fax: (+31 -70) 340-3016

Authorized officer

Hochrein, Marion

INTERNATIONAL SEARCH REPORT

International application No

PCT/US2010/025274

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2007/100462 A1 (LANG PHILIPP [US] ET AL) 3 May 2007 (2007-05-03) figures 1b, 1c, 2h, 2i, 2t, 3g, 3j, 4g, 4i, 5e, 6, 9, 11a, 12a, paragraphs [0052], [0058], [0061], [0193], [0194], [0196] - [0204], [0206] - [0208] -----	1-16

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2010/025274

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of additional fees.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-16, 50

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-16, 50

A method of designing a patient-specific orthopedic implant

2. claims: 17-32

A method of engineering an articular surface

3. claims: 33-49

A method of designing a patient-specific instrument

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2010/025274

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 2008021494 A2	21-02-2008	EP 2083758 A2	05-08-2009
US 2003236473 A1	25-12-2003	NONE	
US 2007118243 A1	24-05-2007	WO 2007045000 A2	19-04-2007
US 2007100462 A1	03-05-2007	AU 2006297137 A1	12-04-2007
		CA 2623834 A1	12-04-2007
		EP 1928359 A2	11-06-2008
		JP 2009513187 T	02-04-2009
		WO 2007041375 A2	12-04-2007

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION See paragraph 2 below

International application No.
PCT/US2010/025274

International filing date (day/month/year)
24.02.2010

Priority date (day/month/year)
24.02.2009

International Patent Classification (IPC) or both national classification and IPC
INV. A61F238 A61F230
ADD. A61B19/00

Applicant
CONFORMIS, INC.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office

D-80296 Munich
Tel. +49 89 2399 - 0
Fax: +49 89 2399 - 4465

Date of completion of
this opinion

see form
PCT/ISA/210

Authorized Officer

Hochrein, Marion

Telephone No. +49 89 2399-5720



WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025274

Box No.	Basis of the opinion
---------	----------------------

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
 - a. (means)
 - ☐ on paper
 - ☐ in electronic form
 - b. (time)
 - ☐ in the international application as filed
 - ☐ together with the international application in electronic form
 - ☐ subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/025274

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of

- ☐ the entire international application
- ☒ claims Nos. 17-49

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international search (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):
- ☒ no international search report has been established for the whole application or for said claims Nos. 17-49
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b).
- ☐ See Supplemental Box for further details

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/025274

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has, within the applicable time limit.
- ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☒ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
 - ☒ not complied with for the following reasons:
see separate sheet
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-16, 50

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>6, 14-16, 50</u>
	No: Claims	<u>1-5, 7-13</u>
Inventive step (IS)	Yes: Claims	<u>50</u>
	No: Claims	<u>1-16</u>
Industrial applicability (IA)	Yes: Claims	<u>1-16, 50</u>
	No: Claims	

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/025274

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item IV.

- 1 This Authority considers that the application does not meet the requirements of unity of invention and that there are 3 inventions covered by the claims indicated as follows:
 1. Claims: 1-16, 50: A method for designing a patient-specific orthopedic implant
 2. Claims: 17-32: A method for engineering an articular surface
 3. Claims: 33-49: A method for designing a patient-specific instrument
- 2 They are not so linked as to form a single general inventive concept (Rule 13.1 PCT) for the following reasons:
- 3 The features shown below are common to the two groups of inventions and are commonly known in the art, for example D1 discloses (the references in parentheses applying to D1):

A method of automatically designing a patient-specific orthopedic implant using a computer system (par. 177), comprising:

obtaining image data of a portion of a patient's anatomy (par. 179; par. 183);
creating a virtual model of the portion of the patient's anatomy (par. 179, 180; par. 186); and
processing automatically the virtual model (par. 179; par. 186).
- 4 The differing features are:
 - 1) the processing of the virtual model is performed to design a patient-specific implant based at least in part on the virtual model
 - 2) the part of the patient's anatomy is a patient's articular surface; and the processing of the virtual model is performed to engineer an articular surface for a patient specific implant based at least in part on the virtual model
 - 3) the part of the patient's anatomy is a patient's joint; and the processing of the virtual model is performed to design a patient-specific instrument based at least in part on the virtual model
- 5 The differing features of each group address different objective technical problems:
 - 1) How to design a patient-specific implant
 - 2) How to engineer an articular surface
 - 3) How to design a patient-specific instrument

- 6 Therefore, these groups of claims have no common "special technical features" nor are they linked by a common inventive concept. The requirements of unity of invention as set forth in Rule 13.1 and 13.2 PCT are not complied with. Accordingly, a partial search report has been drafted covering only the first invention. The applicant is invited to pay two additional search fee under the provisions of Rule 68.2 PCT.

Re Item V.

- 7 Reference is made to the following documents:
- D1 WO 2008/021494 A2 (SMITH & NEPHEW INC [US]; MC COMBS DANIEL L [US]; MELTON MARK [US]; JAM) 21 February 2008 (2008-02-21)
 - D2 US 2003/236473 A1 (DORE SYLVIE [CA] ET AL) 25 December 2003 (2003-12-25)
 - D3 US 2007/118243 A1 (SCHROEDER JAMES [US] ET AL) 24 May 2007 (2007-05-24)
 - D4 US 2007/100462 A1 (LANG PHILIPP [US] ET AL) 3 May 2007 (2007-05-03)
- 8 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. D1 discloses:
- A method of automatically designing a patient-specific orthopedic implant using a computer system (par. 177), comprising:
- obtaining image data of a joint of a patient (par. 179; par. 183);
- creating a virtual model of at least a portion of the patient's joint from the image data (par. 179, 180; par. 186); and
- processing automatically the virtual model to design a patient-specific implant based at least in part on the virtual model (par. 179; par. 186).
- 9 Furthermore, the subject-matter of independent claim 1 is also disclosed by D2, D3, and D4, see passages of these documents cited in the search report.

- 10 The subject-matter of independent claim 50 is also disclosed in D1. The first three steps are generalizations of the steps of claim 1 and are disclosed in D1, see point 8 of this communication. The last step "adjusting the design to meet predetermined parameters" is also disclosed in D1 (D1: par. 190). Claim 50 is therefore not new (Article 33(2) PCT).
- 11 The subject-matter of dependent claims 2 & 4 (D1: par. 186), 3 (D1: par. 190), 5 & 7 (D1: par. 186), 8 & 9 (D1: par. 186), 10 (D1: par. 184), 13 (D1: par. 179) is also not novel.
- 12 In claims 6, 7, 11, 12, 14 - 16, slight constructional changes in the method of claim 1 are defined which come within the scope of the customary practice followed by persons skilled in the art, especially as the advantages thus achieved can readily be foreseen, see passages of D1 cited in the search report. Consequently, the subject-matter of these claims lacks an inventive step (Article 33(3) PCT).

Re Item VII.

- 13 Claim 1 is not drafted in the two-part form with the features disclosed in D1 in the preamble (Rule 6.3 PCT).
- 14 Reference signs in parentheses are not placed behind the corresponding features of the claims (Rule 6.2(b) PCT).
- 15 The closest prior art, D1 - D4, is not cited in the description (Rule 5.1(a)(ii) PCT).

Re Item VIII.

- 16 The first invention comprises two independent apparatus claims. Although the apparatus claims 1 and 50 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter and to differ from each other only with regard to the definition of the subject-matter for which protection is sought and/or in respect of the terminology used for the features of that subject-matter. The aforementioned claims therefore lack conciseness. Moreover, lack of clarity of the claims as a whole arises since the plurality of independent claims makes it difficult if not impossible to determine the matter for which protection is sought and places an undue burden on others seeking to establish the extent of the protection. Hence, the above claims do not meet the requirements of Article 6 PCT.
- 17 Claim 1 does not meet the requirements of Article 6 PCT because the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved ("processing

automatically ... to design ..."), which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.

Furthermore, it is not clear (Article 6 PCT) if the step of designing an implant forms part of claim 1.

- 18 Claim 5 lacks clarity (Article 6 PCT) because it refers back to the known "step of process" which has not been introduced before. It appears that the step "processing automatically ..." of claim 1 is meant.
- 19 Claim 7 lacks clarity (Article 6 PCT) because the feature "generic model containing to create ..." is not clear.
- 20 Claim 15 lacks clarity (Article 6 PCT) because "computer system automatically designs in attachment features" does not make sense.

Possible steps after receipt of the international search report (ISR) and written opinion of the International Searching Authority (WO-ISA)

General information	<p>For all international applications filed on or after 01/01/2004 the competent ISA will establish an ISR. It is accompanied by the WO-ISA. Unlike the former written opinion of the IPEA (Rule 66.2 PCT), the WO-ISA is not meant to be responded to, but to be taken into consideration for further procedural steps. This document explains about the possibilities.</p>
Amending claims under Art. 19 PCT	<p>Within 2 months after the date of mailing of the ISR and the WO-ISA the applicant may file amended claims under Art. 19 PCT directly with the International Bureau of WIPO. The PCT reform of 2004 did not change this procedure. For further information please see Rule 46 PCT as well as form PCT/ISA/220 and the corresponding Notes to form PCT/ISA/220.</p>
Filing a demand for international preliminary examination	<p>In principle, the WO-ISA will be considered as the written opinion of the IPEA. This should, in many cases, make it unnecessary to file a demand for international preliminary examination. If the applicant nevertheless wishes to file a demand this must be done before expiry of 3 months after the date of mailing of the ISR/ WO-ISA or 22 months after priority date, whichever expires later (Rule 54bis PCT). Amendments under Art. 34 PCT can be filed with the IPEA as before, normally at the same time as filing the demand (Rule 66.1 (b) PCT).</p> <p>If a demand for international preliminary examination is filed and no comments/amendments have been received the WO-ISA will be transformed by the IPEA into an IPRP (International Preliminary Report on Patentability) which would merely reflect the content of the WO-ISA. The demand can still be withdrawn (Art. 37 PCT).</p>
Filing informal comments	<p>After receipt of the ISR/WO-ISA the applicant may file informal comments on the WO-ISA directly with the International Bureau of WIPO. These will be communicated to the designated Offices together with the IPRP (International Preliminary Report on Patentability) at 30 months from the priority date. Please also refer to the next box.</p>
End of the international phase	<p>At the end of the international phase the International Bureau of WIPO will transform the WO-ISA or, if a demand was filed, the written opinion of the IPEA into the IPRP, which will then be transmitted together with possible informal comments to the designated Offices. The IPRP replaces the former IPEA (international preliminary examination report).</p>
Relevant PCT Rules and more information	<p>Rule 43 PCT, Rule 43bis PCT, Rule 44 PCT, Rule 44bis PCT, PCT Newsletter 12/2003, QJ 11/2003, QJ 12/2003</p>